

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mason et al.

Serial No: 09/230,955

Examiner: B Brumback

Filed: May 4, 1999

Art Unit: 1642

For: ASSESSMENT OF CERVICAL CELLS

DECLARATION

I, Christopher Harold Holmes, a British citizen of 13 Sunnyside, Stoke Bishop, Bristol BS9 1BQ, United Kingdom, do hereby declare and state as follows:

1. I hold a B.Sc. in Biological Sciences (University of East Anglia, Norwich, UK) and a Ph.D. (Medical Sciences, University of Nottingham, UK). I am Senior Lecturer in the Division of Obstetrics and Gynaecology in the Department of Clinical Medicine at the University of Bristol, UK and head of the Human Development Research Group which has dedicated research laboratories, including a hybridoma production facility, in St. Michael's Hospital Bristol, UK. I have held substantial research awards from the Cancer Research Campaign, Medical Research Council, Wellcome Trust and, currently, the Integrated Healthcare Technology Programme of the UK Engineering and Physical Sciences Research Council. I have acted as External Examiner for Doctoral degrees at the Universities of Melbourne, Australia and Bergen, Norway as well as several UK Universities. I have published over 50 peer reviewed articles in journals that include Cancer Research, International Journal of Cancer,

Carcinogenesis, American Journal of Pathology, Proceedings of the National Academy of Sciences USA, and the Journal of Immunology.

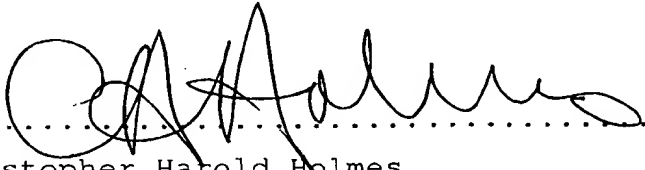
2. I am a co-inventor of US Application 09/230,955.
3. I have read and understood the Office Action dated November 11, 2001. On page 6, last line through to page 7, line 4 of that Office Action the Examiner states:

"There does not appear to be any data whatsoever regarding differentiation of neoplastic specimens from normal specimens. Lastly, applicant's claims are drawn to a method of screening for a premalignant or neoplastic disease. Methods of clinical diagnosis of premalignant and neoplastic disease are clearly envisioned and encompassed within applicant's claimed method".

4. Table 4, page 55 of Application 09/230,955 presents results of the reactivity of the monoclonal antibodies with cervical smears from premalignant specimens.
5. The terms "neoplastic" and "pre-malignant" were used interchangeably within the field of cervical cancer disease detection at the filing date of Application 09/230,955. One of ordinary skill in the art would view these terms to be equivalent, and to refer to the same disease status. Both could be used interchangeably to refer to CIN I, II or III.
6. Thus, Table 4, page 55 of Application 09/230,955 presents data regarding the differentiation of neoplastic specimens, this being equivalent to premalignant specimens.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of title 18 of the United States Code and that such wilful false statements may jeopardise the validity of the abovementioned Application or any Patent issued thereon.

Signed:


Christopher Harold Holmes

Date:

28th January 2003